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PATENT ATTORNEY DOCKET: 46884-5275

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| ffi re Application of:                                    | )                                  |
|---|------------------------------------|
| Kazunori YAMAUCHI   | ) Confirmation No.: 8361           |
| Application No.: 10/785,412                               | ) Group Art Unit: 2877             |
| Filed: February 25, 2004                                  | ) Examiner: Richard A. Rosenberger |
| For: MEASURING DEVICE FOR IMMUNOCHROMATOGRAPHY TEST PIECE | ,                                  |

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Window
Alexandria, VA 22314

Sir:

# SUBMISSION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Applicant brings to the attention of the Examiner the attached document.

Attached is an English-language translation of an International Preliminary Examination Report ("IPER") dated March 9, 2006 that issued in a related PCT/JP2004/002248 application. Applicants respectfully request that the Examiner consider the IPER as it relates to the above-identified application.

While the IPER cites to three particular documents (D1-D3), these documents are not attached hereto because they were previously filed in Information Disclosure Statements in this application on October 27, 2004.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or

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constitute "prior art." If it should be determined that any of the listed documents do not

constitute "prior art" under United States law, Applicant reserves the right to present to the office

the relevant facts and law regarding the appropriate status of such document.

Applicant further reserves the right to take appropriate action to establish the patentability

of the disclosed invention over the listed documents, should one or more of the documents be

applied against the claims of the present application.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby

authorized by this paper to charge any additional fees during the entire pendency of this

application including fees due under 37 C.F.R. § 1.16 and 1.17 which may be required, including

any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310.

This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF

TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

DRINKER, BIDDLE & REATH LLP

Dated: May 2, 2006

By:

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#### From the INTERNATIONAL BUREAU

### PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER 1 OR CHAPTER II
OF THE PATENT COOPERATION TREATY)

(PCT Rules 44bis.3(c) and 72.2)

| То:   |      |                   |
|---|------|-------------------|
| HASEGAWA, Yoshiki<br>Soei Patent And Law F<br>10-5, Ginza 1-chome<br>Chuo-ku<br>Tokyo, 1040051<br>JAPON | Firm | Ginza First Bldg. |
| <u> </u>  |      | <u> </u>          |

Date of mailing (day/month/year)
09 March 2006 (09.03.2006)

Applicant's or agent's file reference
FP04-0005-00

International application No.
PCT/JP2004/002248

Applicant

HAMAMATSU PHOTONICS K.K. et al

| 1. | Transmittal of | the | translation | 10 | the a | pplicant. |
|----|----------------|-----|-------------|----|-------|-----------|
|----|----------------|-----|-------------|----|-------|-----------|

| V | The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter 1). |
|---|---|
|   |   |

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

Yoshiko Kuwahara

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 90 90



### PATENT COOPERATION TREATY

# **PCT**

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

| Applicant's or agent's file reference FP04-0005-00  | FOR FURTHER ACTION  | See item 4 below   |  |  |  |
|---|---|--|--|--|--|
| International application No.<br>PCT/JP2004/002248  | International filing date (daymonth/year) 26 February 2004 (26.02.2004) | Priority date (day/month/year) 26 February 2003 (26.02.2003) |  |  |  |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 |   |  |  |  |  |
| Applicant<br>HAMAMATSU PHOTONICS K.K.   |   |  |  |  |  |

| 1.     | <ol> <li>This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the<br/>International Searching Authority under Rule 44 bis.1(a).</li> </ol>   |   |  |  |  |  |
|--------|---|---|--|--|--|--|
| 2.     | 2. This REPORT consists of a total of 7 sheets, including this cover sheet.   |   |  |  |  |  |
|        | In the attached sheets, any refer<br>to the international preliminary   |   | ion of the International Searching Authority should be read as a reference Chapter I) instead. |  |  |  |
| 3.     | This report contains indications  | relating to the following   | g items:   |  |  |  |
|        | Box No. 1   | Basis of the report   |  |  |  |  |
|        | Box No. II  | Priority  |  |  |  |  |
|        | Box No. III   | Non-establishment of applicability.   | of opinion with regard to novelty, inventive step and industrial                               |  |  |  |
| İ      | Box No. IV  | Lack of unity of inve   | ention   |  |  |  |
|        | Box No. V   | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |  |  |  |  |
|        | Box No. VI  | Certain documents of  | ited   |  |  |  |
|        | Box No. VII   | Certain defects in the  | e international application  |  |  |  |
| ŀ      | Box No. VIII  | Certain observations  | on the international application   |  |  |  |
| 4.     | 4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2). |   |  |  |  |  |
|        |   |   |  |  |  |  |
|        |   |   | Date of issuance of this report<br>02 March 2006 (02.03.2006)                                  |  |  |  |
|        | The International Bure<br>34, chemin des Col  | ombettes  | Authorized officer Yoshiko Kuwahara  |  |  |  |
| Facsin | 1211 Geneva 20, Sy<br>nile No. +41 22 740 14 35   | vitzerland  | Telephone No. +41 22 338 90 90   |  |  |  |
|        | CT/IR/373 (January 2004)  | <del></del>   |  |  |  |  |

## PATENT COOPERATION TREATY

| From the INTERNATIONAL SEARCHING AUTHOR  | иту   |                                  |  |  |  |
|--|---|----------------------------------|--|--|--|
| Io:  |   |                                  | PCT PCT  |  |  |
|  |   |                                  | ITTEN OPINION OF THE<br>IONAL SEARCHING AUTHORITY  |  |  |
|  |   |                                  | (PCT Rule 43bis.1)   |  |  |
|  |   | Date of mailing (day/month/year) | 20.04.2004   |  |  |
| Applicant's or agent's file reference  |   | FOR FURTHER A                    | CTION  |  |  |
| FP04-0005-0  | 0 0   |                                  | See paragraph 2 below  |  |  |
| International application No.  | International filing date (   | day/monsh/year)                  | Priority date (day/month/year)   |  |  |
| PCT/JP2004/002248  | 26.02.2004  |                                  | 26.02.2003   |  |  |
| International Patent Classification (IPC) or both G01N21/17  Applicant   | n national classification an  | d IPC                            |  |  |  |
| HAMAMATSU PHOTONICS F  | K.K. et al  |                                  |  |  |  |
| This opinion contains indications relat  | ting to the following items   |                                  |  |  |  |
| Box No. 1 Basis of the   | •   |                                  |  |  |  |
| Box No. II Priority  |   |                                  |  |  |  |
| Box No. III Non-establis   | haneat of opinion with reg  | ard to novelty, inventiv         | e step and industrial applicability  |  |  |
|  | y of invention  |                                  |  |  |  |
| Box No. V Reasoned sta   | mement under Rule 43bis.;<br>; citations and explanation  | l(a)(i) with regard to no        | ovelty, inventive step or industrial<br>ment   |  |  |
| Box No. VI Certain docu  |   | -                                | ĺ  |  |  |
| Box No. VII Certain defe   | cts in the international app  | lication                         |  |  |  |
| Box No. VIII Certain obser   | rvations on the internation   | al application                   |  |  |  |
| 2 FURTHER ACTION   |   |                                  |  |  |  |
| International Preliminary Examining A<br>than this one to be the IPEA and the  | If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. |                                  |  |  |  |
| If this opinion is, as provided above,<br>written reply together, where approp<br>PCT/ISA/220 or before the expiration | riate, with amendments, b   | before the expiration o          | the applicant is invited to submit to the IPEA a of 3 months from the date of mailing of Form pires later. |  |  |
| For further options, see Form PCT/ISA/220.   |   |                                  |  |  |  |
| 3. For further details, see notes to Porm P  | CT/1SA/220.   |                                  |  |  |  |
| Name and mailing address of the ISA/JP   |   | Authorized officer               |  |  |  |
|  |   | - Landon Maria Villa Ca          |  |  |  |
|  |   |                                  |  |  |  |
| Facsimile No.  |   | Telephone No.                    |  |  |  |

International application No.
PCT/JP2004/002248

| Box | x No. I Basis of this opinion   |
|-----|---|
| 1.  | With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.   |
|     | This opinion has been established on the basis of a translation from the original language into the following language  |
|     | , which is the language of a translation furnished for the purposes of international search (under  |
|     | Rule 12.3 and 23.1(b)).   |
| 2   | With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claime invention, this opinion has been established on the basis of:   |
|     | a. type of material   |
|     | a sequence listing  |
|     | table(s) related to the sequence listing  |
|     | b. format of material   |
|     | in written format   |
|     | in computer readable form   |
|     | c. time of filing/furnishing  |
|     | contained in the international application as filed.  |
|     | filed together with the international application in computer readable form.  |
|     | furnished subsequently to this Authority for the purposes of search.  |
|     |   |
| 3.  | In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filled or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filled or does not go beyond the application as filled, as appropriate, were furnished. |
| 4.  | Additional comments:  |
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PCT/JP2004/002248

| Gitations and explanations sup |               |                  | porting such statement |         |     |
|--------------------------------|---------------|------------------|------------------------|---------|-----|
| I.                             | Statement     |                  |                        |         |     |
|                                | Novelty (N)   |                  | Claims                 | 1-10    | YES |
|                                |               |                  | Claims                 |         | NO  |
|                                | Inventive se  | ep (IS)          | Claims                 | 7-9     | YES |
|                                |               |                  | Claims                 | 1-6, 10 | NO  |
|                                | Industrial ap | plicability (IA) | Claims                 | 1-10    | YES |
|                                |               |                  | Claims                 |         | NO  |
|                                |               |                  |                        |         |     |

#### 2. Citations and explanations:

Document 1: JP 11-083745 A (Matsushita Electric Industrial Co., Ltd.), 26 March 1999

Document 2: JP 2002-098631 A (Matsushita Electric Industrial Co., Ltd.), 5 April 2002

Document 3: JP 10-288581 A (Nissho Kabushiki Kaisha), 27
October 1998

#### Claim 1

Document 1 sets forth a device for measuring an immunochromatography test piece provided with an illumination optical system containing a semiconductor light-emitting element and a detection optical system containing a semiconductor light-receiving element, wherein the aforementioned illumination optical system and detection optical system are positioned in a direction approximately parallel to the coloring line formed on the immunochromatography test piece.

Document 2 sets forth a device for measuring an immunochromatography test piece, wherein an illumination optical system is positioned in such a manner that an immunochromatography test piece is irradiated in an approximately perpendicular direction, and a detection optical system is positioned in such a manner that light

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Box No. V

Reasoned statement under Rule 43bis 1(aXi) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement

reflected to a diagonally upward direction from an immunochromatography test piece is detected (fig. 1).

It would be easy for a person skilled in the art to apply the positioning of the illumination optical system and the detection optical system with respect to an immunochromatography test piece, in the optical system set forth in document 1.

Therefore the invention set forth in claim 1 does not involve an inventive step in the light of documents 1 and 2.

#### Claim 2

Document 2 sets forth a device for measuring an immunochromatography test piece, wherein the aforementioned illumination optical system is provided with an opening member (corresponding to the "light flux forming member) which forms light having a light flux cross section extending in an approximately parallel direction with the coloring line, and a lens which forms an image of the light from the aforementioned opening member on the aforementioned immunochromatography test piece (page 4, left column, lines 14 to 16 and page 5, left column, lines 16 to 18).

It would be easy for a person skilled in the art to apply the aforementioned opening member and lens in the illumination optical system set forth in document 2 to the illumination optical system set forth in document 1.

Therefore the invention set forth in claim 2 does not involve an inventive step in the light of documents 1 and 2.

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claim 3

Document 1 indicates that a device for measuring an immunochromatography test piece is provided with a housing (corresponding to the "optical head" of the present invention) to which the aforementioned illumination optical system and detection optical system are fitted; a tray (corresponding to the test piece loading table) for placing the immunochromatography test piece, and a scanning mechanism for moving the aforementioned tray and the aforementioned housing relative to one another in a scanning direction traversing the coloring line (fig. 2 and 3).

Therefore the invention set forth in claim 3 does not involve an inventive step in the light of documents 1 and 2.

#### Claims 4 to 6

Document 1 sets forth a device for measuring an immunochromatography test piece, provided with a scanning mechanism which moves the aforementioned housing to which the optical system is attached, and the main body to which said scanning mechanism (corresponding to the "chassis" of the present invention) is provided (page 3, right column, lines 42 to 48; fig. 1).

Therefore the invention set forth in claims 4 to 6 does not involve an inventive step in the light of documents 1 and 2.

#### Claims 7 to 9

None of the documents cited in the international search report indicates that a scanning mechanism which scans a test piece is configured in such a manner that a

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

guide rail is provided to the outside of the chassis and the optical system which moves in a scanning direction along said guide rail is laid across, passing through notches formed in the top plate of the chassis, in order . to achieve the purposes of simplifying the configuration and reducing costs, and it would not be easy for a person skilled in the art to conceive of said configuration.

Therefore the invention set forth in claims 7 to 9 involves an inventive step in relation to the documents cited in the international search report.

#### Claim 10

Document 3 sets forth a device for optically detecting the degree of coloring of a test piece, wherein in order to facilitate washing, the holder (corresponding to the "table" of the present invention) upon which the test piece is placed is detachable with respect to the case (corresponding to the "chassis" of the present invention) (fig. 2 and page 7, left column, lines 38 to 42).

It would be easy for a person skilled in the art to apply the configuration which facilitates washing set forth in document 3, to the device set forth in document 1.

Therefore the invention set forth in claim 10 does not involve an inventive step in the light of documents 1 to 3.